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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,622	05/07/2002	Nicholas Bachynsky	HO-P01615WO0	1907

7590 05/30/2006

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EXAMINER

ROYDS, LESLIE A

ART UNIT PAPER NUMBER

1614

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 09/744,622	Applicant(s) BACHYNSKY ET AL.	
Examiner Leslie A. Royds	Art Unit 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 May 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: 58, 59 and 61-63.
Claim(s) rejected: 1-5, 7-14 and 57-60.
Claim(s) withdrawn from consideration: 55 and 56.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s) _____.
13. ☐ Other: _____.

Leslie A. Royds
Patent Examiner
Art Unit 1614

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Continuation of 3. NOTE:

Applicant's after-final amendment proposes the cancellation of pending claims 1-5, 7-14 and 55-63 in lieu of newly added claims 64-85, drawn to methods for inducing intracellular hyperthermia in a subject to treat or diagnose cancer selected from the group consisting of prostate carcinoma, glioblastoma multiforme, Kaposi's sarcoma, peritoneal carcinomatosis or glioma (claims 64-72), methods for inducing intracellular hyperthermia in a subject to treat or diagnose infections that result from *Borrelia burgdorferi*, *Mycobacterium leprae*, *Treponema pallidum*, HIV, Hepatitis C, herpes virus or papillomavirus (claims 73-79), or methods for inducing intracellular hyperthermia in a subject to treat or diagnose an infestation resulting from *Candida*, *Sporothrix schenckii*, *Histoplasma*, *paracoccidioides*, *Aspergillus*, *Leishmania*, malaria, *acanthamoeba* or cestodes (claims 80-85) comprising administering an amount of a mitochondrial uncoupling agent sufficient to induce whole body intracellular hyperthermia in the subject.

The proposed amendments raise new issues that would require further consideration and/or search were such amendments to be entered into the record. In particular, it is noted that the proposed claims were examined insofar as they read on the combination of 2,4-dinitrophenol as the mitochondrial uncoupling agent and glucagon as the second therapeutic agent. However, the proposed claim amendments are not limited to the subject matter that was elected pursuant to Applicant's notice of election dated November 8, 2004, but rather are drawn to numerous other species of mitochondrial uncoupling agent and additional therapeutic agents that were not previously searched and considered during the course of prosecution. In other words, entry of the proposed claim amendments would necessitate the search and consideration of the additional species recited in the claims, which is considered a new issue. In light of this, it is, thus, proper to deny entry of the proposed claim amendments.

In addition, the proposed claim amendments are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal because they raise new issues that require consideration under 35 U.S.C. 101, 102, 103 and 112 and the additional search and examination of new species that were not previously considered or searched.

For these reasons, the proposed amendments to the claims will not be entered.

Continuation of 11. does NOT place the application in condition for allowance because:

Regarding the remarks that Applicant has presented accompanying the proposed amendments, each of the remarks is directed to the fact that objected and/or rejected claims have been cancelled and, thus, the objection or rejection should be withdrawn. However, for the reasons stated above, the claim amendments will not be entered and the claims remain rejected for the reasons of record as set forth in the final rejection of November 30, 2005. Applicant's attention is directed thereto. Insofar as Applicant has not presented any arguments regarding the traversal of each of the objections and rejections set forth in the final rejection, the objections and rejections remain proper and are maintained.

For these reasons, the proposed amendments to the claims will not be entered. The claims remain objected to and/or rejected for the reasons previously set forth in the final rejection of November 30, 2005.

Ardin H. Marschel 5/26/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER